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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 9151-26

CERTIFICATION OF TRANSMISSION

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Signature Cara L. Rose

Typed or printed name Cara L. Rose

Application Number	Filed
10/629,259	July 29, 2003

First Named Inventor: Craig A. Hamilton

Art Unit	Examiner
3768	Amanda L. Lauritzen

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☒ attorney or agent of record. Registration number 40,142
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

Signature

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March 10, 2008
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

Attorney Docket No.: 9151-26 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Hamilton et al. Confirmation No.: 6693
Application Serial No.: 10/629,259 Group Art Unit: 3768
Filed: July 29, 2003 Examiner: Amanda L. Lauritzen
Title: CARDIAC DIAGNOSTICS USING TIME COMPENSATED STRESS TEST CARDIAC MRI IMAGING AND SYSTEMS FOR CARDIAC DIAGNOSTICS

Date: March 10, 2008

REMARKS IN SUPPORT OF REQUEST FOR PRE-APPEAL BRIEF REVIEW

This document is submitted in support of the Pre-Appeal Brief Request For Review filed concurrently with a Notice of Appeal for the above-referenced patent application. No amendments are being filed with this Request. Applicants hereby request a review of finally rejected Claims 1-34. This request notes the clear error in facts and/or the absence of elements needed for a *prima facie* rejection of the pending claims.

A. The Claims Comply with the Written Description Requirement.

The Action rejects Claims 1-20, 24, 25, 29, 30 and 32 for failing to comply with the written description requirement. More particularly, the Action alleges that the recitation in Claim 1 of "displaying a plurality of the adjusted MRI cine loops at a clinician workstation in substantially real-time *while the patient is in an MRI scanner* used for the acquiring step" is not clearly pointed out in the specification.

Applicants submit that the application does provide sufficient support that reasonably conveys to one of skill in the art that the inventors had possession of the claimed invention. Specifically, the specification recites at p. 13:

> In particular embodiments of the present invention, the display of cine loops is provided in real time. In other embodiments, the display of cine loops is provided in near real time. Such real time or near real time display of cine loops of a patient undergoing stress testing may be utilized to provide safe stress testing by allowing for rapid analysis and monitoring of the stress test such that patient injury may be avoided.

The specification also states at page 12, lines 7-11, that the evaluation process can be performed in a sufficiently real-time manner so as to allow a physician to utilize the MRI cine loops to monitor a stress test while the stress test is being performed. Such monitoring can provide early evidence of inducible ischemia to allow a physician to assess cardiac physiology of a patent so as to adjust parameters of the test and/or avoid injury to the patient, thereby providing safe stress testing as described for example, at pp.12 and 13.

Applicants respectfully submit that at least the above text clearly conveys that the patient is in the scanner during the clinician evaluation. Indeed, one of skill in the art would readily acknowledge and understand that both the described rapid analysis and monitoring in real or near real time as well as the ability to adjust test parameters to avoid injury are done while the patient is in the scanner. Set-up of a patient within the high-field magnet of MRI scanners is not instantaneous. Applicant submits that one of skill in the art would fully understand that to provide substantially real-time display during a stress test, the patient must remain inside the scanner/magnet bore.

The Action also states the recitations in Claim 1 and 32 specifying display "during the stress test" to "adjust parameters...to avoid injury" are also "not wholly supported" and that there is no "reasonable expectation" for such details to be inferred. Again, Applicant strongly disagrees and directs the Examiner's attention to at least the passages noted above. Particularly, the description at pp. 13, lines 19-24 states:

> In particular embodiments of the present invention, the display of cine loops is provided in real time. In other embodiments, the display of cine loops is provided in near real time. Such real time or near real time display of cine loops of a patient undergoing stress testing may be utilized to provide safe stress testing by allowing for rapid analysis and monitoring of the stress test such that patient injury may be avoided.

(emphasis added). Page 12, lines 4-14 also states:

> As discussed above, it has been found that the temporal synchronization process described herein allows for such a display without introducing inaccuracies, artifacts or other such distortions that would hinder the evaluation process. Furthermore, the evaluation process may be performed in a sufficiently real-time manner so as to allow a physician to utilize the MRI cine loops to monitor a stress test while the stress test is being performed. Such monitoring may be useful both in administering the stress test and in evaluation of a patient's condition based on the results of the stress test. By providing the cine loop information in a form that allows for simultaneous direct comparison of data for differing heart rates a physician may rapidly assess the cardiac physiology of a patient so as to adjust parameters of the test and/or avoid injury to the patient.

(emphasis added). Clearly, these claimed features are sufficiently supported by the specification.

With regard to Claim 29, the Action states that the application does not describe "registration of loops in relation to common physical locations of the heart, nor is it specified to take place prior to comparison." However, at page 12 (lines 30-33), the application states:

> Such a registration may be provided utilizing conventional pattern recognition and/or alignment techniques such that corresponding pixels of the cine loops or portions of the cine loops are each associated with approximately the same physical location within the patient.

Applicants reiterate the fact that Claim 29 as presented in the last response (submitted September 11, 2007) recites this language from the specification nearly verbatim. Accordingly, Applicants respectfully submit that one skilled in the art would read the present application and conclude that the inventors were in possession of a method wherein the patient is in the scanner during the clinician evaluation as recited by Claim 1 and wherein the registration of the baseline loops to cine loops can be provided such that corresponding pixels are associated with the same physical location as recited by Claim 29.

Claims 24, 25 and 30 also stand rejected for lack of support in the written description. However, the Action fails to indicate the reasoning for this since these claims as presented in the last response (submitted September 11, 2007) no longer recite the language that was specifically objected to. No further reasoning was provided in the subsequent Office Action dated January 10, 2008, for maintaining this rejection with regard to these particular claims. Thus, for at least the foregoing reasons, Applicants respectfully request that the present application be reviewed and that the written description rejections of Claims 1-20, 24, 25, 29 and 30 be withdrawn by the pre-appeal brief review conference prior to the filing of an appeal brief.

B. The Presently Claimed Invention is Non-Obvious over Lobodzinski et al. in View of Epstein and the other cited secondary references.

Claims 1-10, 12-19, 25-29 and 31-34 stand rejected as being obvious over U.S. Patent No. 5,619,995 ("Lobodzinski") over one or more secondary and/or tertiary references.

Claim 1 as presented herein recites a method of cardiac diagnostics of a patient, wherein a plurality of different views of MRI cine-loops of the heart of the patient at a plurality of heart rates is acquired and further wherein each MRI cine loop has substantially the same duration; displaying a plurality of the adjusted MRI cine loops at a clinician workstation *in substantially real-time while the patient is in an MRI scanner* used for the acquiring step; allowing a clinician to electronically select at least one of the following: (a) at least one dose amount; (b) at least one view; or (c) at least one dose amount and at least one view to define the MRI cine loops for the

displaying step; and evaluating the compensated MRI cine loops so as to assess a state of coronary physiology of the patient.

Lobodzinski is directed to "video" signals **not** MRI cine loops as claimed in the present invention. Lobodzinski states that "[t]he system of the present invention utilizes real-time image compression to store digitized video to a disc media in a continuous real-time fashion, thus making it possible to store the entire study with no possibility of losing data." (col. 5, lines 19-25). Lobodzinski states that "DIS generates a video signal 14 .... Other DIS may be ... a cardiac MRI apparatus.... The video signal can be generated in either analog or digital form. A Video Processor (VP) is in communication with the DIS for receiving the video signal." (col 8, lines 6-15).

Lobodzinski discusses various prior art methods such as X-ray angiography (col. 2, lines 37) and characterizes them as being different, because they use only selected still images (col. 2, lines 40-45) and do not utilize real-time video compression. Lobodzinski also states that its proposed methods are distinctively different from the described methods of stress echocardiography (col. 5, lines 15-18). Thus, Lobodzinski stresses the technical differences of video versus still images used for cine, such as those used with MRI cine loops (col. 2, lines 34-45, and col. 5, lines 10-25).

The instant invention does not employ a video signal coming from the MR scanner, but rather employs separate digital snapshots of the heart taken at various times. As Lobodzinski states with respect to technologies that use still images, Applicants submit that the reverse is also true: the instant invention is "distinctively different" from the real-time video compression system proposed by Lobodzinski. MRI builds up a collection of snapshots of the heart at various points in the cardiac cycle, but these snapshots require many heartbeats to acquire, and, hence, are simply representative of typical images of the heart averaged over those many heartbeats. Further, there is only one set of frames spanning the one 'representative' heart cycle. In a video stream, there is a real-time stream of many heartbeats.

With respect to the fact that Lobodzinski states that MRI may be used (col. 8, line10), Applicants respectfully submit that, in the past, the MRI cine loops for cardiac stress analysis were asynchronous; that is, the MRI data for the cine loops was collected, then manipulated at a later time. In contrast, the present invention discloses synchronized, adjusted MRI cine loops that are displayed in substantially real-time. Further, with regard to cine loops, Lobodzinski states nothing more than "most diagnostic imaging systems provide some sort of cine loop review." (col. 2, lines 3-6) Notably, Lobodzinski goes on to also state that, "they typically do

not provide digital motion video recording, serial comparison, and display functions." (*Id.*, emphasis added). Applicants submit that Lobodzinski's repeated discussions about the differences between the continuous real time video image compression technology as claimed therein from other motion video or the use still or selected images to form cine loops (col. 2, lines 33-45, col. 5, lines 10-25), in fact, teach away from the claimed subject matter.

Furthermore, Claim 1 also recites that the cine loops are displayed *during the stress test* to allow a physician to assess cardiac physiology of a patent so as to adjust parameters of the test and/or avoid injury to the patient thereby providing safer cardiac stress testing. Lobodzinski fails to teach or suggest providing synchronized, adjusted MRI cine loops that are displayed in substantially real-time, much less while a patient is in an MRI scanner as taught by the present invention. Such monitoring as taught by the present invention can provide early evidence of inducible ischemia to allow a physician to assess cardiac physiology of a patent so as to adjust parameters of the test and/or avoid injury to the patient, thereby providing safe stress testing as described for example, at pp.12 and 13 of the specification. Embodiments of the present invention now generate the cine loops using multiple MRI images during a cardiac cycle that form the frames of a cine loop (this is **not** a real-time video stream as taught by Lobodzinski), during a stress test in a manner that allows for safe and more accurate cardiac stress tests. The generation of substantially real-time MRI cine loops to allow for improved safety during cardiac stress testing is novel and non-obvious over the cited prior art.

Accordingly, Applicants respectfully submit that Lobodzinski fails to teach or suggest the present invention and, in fact, it teaches away from the present invention. Further, the cited secondary references fail to remedy the deficiencies of Lobodzinski. As such, Applicants respectfully request that the present application be reviewed and that the rejection of Claims 1-34 be reversed by the pre-appeal brief conference prior to the filing of an appeal brief.

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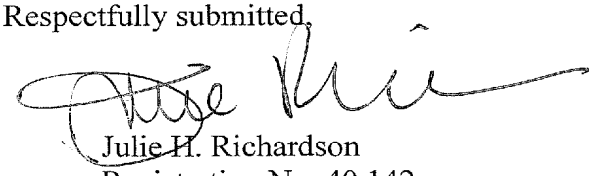
Respectfully submitted,



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